

Definitions of Criteria and Considerations for K Applications

The guidelines available here use language posted in the original funding opportunity announcement (FOA) and do not replace or modify the criteria established in the full announcement. If you have any questions, contact the Scientific Review Officer (SRO) in charge of the review panel. SRO contact information for your application can be found in [eRA Commons](#).

Overall Impact

Reviewers should provide an overall impact critique to reflect their assessment of the likelihood for the candidate to maintain a strong research program, taking into consideration the criteria below in determining the overall impact/priority score. Your critique should indicate the most significant strengths and weaknesses.

Additional guidance for K01, K08, K23:

Reviewers should recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator.

Additional guidance for K24:

Although it is understood that currently funded research described in K24 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided.

Research proposed in the K24 application that is not currently funded by a peer-reviewed grant should include a Statement of Hypothesis and Specific Aims; Background, Preliminary Studies and Aims. In addition, the application should outline the general goals for the later years and sufficient detail should be provided to permit evaluation of the scientific merit of the plan.

Additional guidance for K25:

Reviewers should recognize that an individual with limited research experience is less likely to be able to prepare a research plan with the breadth and depth of that submitted by a more experienced investigator. Although it is understood that K25 applications do not require the level of detail necessary in regular research grant applications, a fundamentally sound research plan must be provided. In general, less detail is expected with regard to research planned for the later years of the award, but the application should outline the general goals for these years.

SCORED REVIEW CRITERIA

Reviewers will consider each of the five review criteria below in the determination of scientific and technical merit, and give a separate score for each.

1. Candidate

K01 and K08:

- Does the candidate have the potential to develop as an independent and productive researcher?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

K23:

- Does the candidate have the potential to develop as an independent and productive researcher

focusing on patient-oriented research?

- Is the candidate's academic, clinical, and (if relevant) research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator focusing on patient-oriented research?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

K24:

- Is there evidence of ongoing high quality patient-oriented research, and what is the relationship of that research to this K24 proposal?
- Is there evidence of the candidate's capabilities and commitment to serve as a mentor for new clinical investigators in the conduct of patient-oriented research?
- Does the application demonstrate that the proposed program and protected time will relieve the candidate from non-research patient care and administrative duties and allow him/her to devote additional time and to augment his/her capabilities in patient-oriented research?
- Does the application demonstrate a record of independent peer-reviewed support for patient-oriented research that is likely to continue during the K24 award?

K25:

- Does the candidate have the potential to develop as an independent and productive quantitative biomedical, behavioral, bioimaging or bioengineering researcher or to play a significant role in multi-disciplinary research teams?
- Is the candidate's academic, clinical (if relevant), and research record of high quality?
- Is there evidence of the candidate's commitment to meeting the program objectives to become an independent investigator in research?
- Do the letters of reference from at least three well-established scientists address the above review criteria, and do they demonstrate evidence that the candidate has a high potential for becoming an independent investigator?

K99:

- What is the candidate's record of research productivity, including the quality of peer-reviewed scientific publications?
- What is the quality of the candidate's pre- and postdoctoral research training experience, including expertise gained?
- Based on the postdoctoral candidate's experience, track record and prior research training, what is the candidate's potential to become an outstanding, successful independent investigator who will contribute significantly to his/her chosen field of biomedical-related research?
- To what extent does the application provide evidence of the candidate's research creativity, and does this evidence suggest that the candidate has the potential to develop a creative, independent research program?
- Evaluate the letters of reference. Are there letters from at least three well-established scientists?
- Relative to the above review criteria, how do these scientists evaluate the candidate? Do the letters provide strong evidence that the candidate has a high potential to become an independent investigator?
- Given the candidate's prior training, proposed career development plan, and the referees' evaluations, is it reasonable to expect that the candidate will be able to achieve an independent, tenure-track or equivalent position within the time period requested for the K99 phase of this award?

2. Career Development Plan/Career Goals & Objectives (K24 Only - Plan to Provide Mentoring)

K01 and K08:

- What is the likelihood that the plan will contribute substantially to the scientific

development of the candidate leading to scientific independence?

- Is the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated training and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

K23:

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the candidate's prior training and research experience appropriate for this award?
- Are the goals and scope of the plan when considered in the context of prior training/research experience and the stated training and research objectives, appropriate?
- Are the content and duration of the proposed didactic research activities during the proposed award period clearly stated and appropriate?
- Are there adequate plans for evaluating the candidate's research and career development progress?

K24:

- Are the plans to provide mentoring or supervising new clinical investigators in patient oriented research adequate?
- Are plans to integrate appropriate clinical research curricula, such as those offered by available K30 programs at the institution, into the mentoring plans adequate?
- Is an appropriate level of effort proposed for the mentoring component?

K25:

- What is the likelihood that the plan will contribute substantially to the scientific development of the candidate leading to scientific independence?
- Is the content, scope, phasing, and duration of the career development plan appropriate when considered in the context of prior training/research experience and the stated didactic and research objectives for achieving research independence?
- Are there adequate plans for monitoring and evaluating the candidate's research and career development progress?

K99:

- Are the content and duration of the proposed didactic and research components of the career development plan appropriate for the candidate's current stage of scientific and professional development and proposed research career goals?
- Is the proposed career development plan likely to contribute substantially to the scientific and professional development of the candidate including his/her successful transition to independence? For individuals currently supported by research training programs, how does the proposed career development plan enhance or augment the applicant's training to date?
- Is the additional proposed training needed and appropriate for the proposed research plan and the applicant's future career plans?
- To what extent are the plans for evaluating the K99 awardee's progress adequate and appropriate for guiding the applicant towards a successful transition to the independent phase of the award?
- Is the timeline planned for the transition to the independent phase of the award appropriate for the candidate's current stage of scientific and development and the career development proposed for the K99 phase of the award?

K01 and K08:

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

3. Research Plan

K23:

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives focusing on patient-oriented research?
- Is the plan for developing/enhancing the candidate's research skills appropriate and adequate?

K24:

- Is the research plan an appropriate vehicle for demonstrating and developing the prospective mentee's skills and capabilities in patient-oriented research?
- Are the scientific and technical plans of the proposed research of merit?
- Is the proposed research relevant to the candidate's career objectives?
- Are adequate resources available to conduct the research program? This includes adequacy of plans for continued support of the research during the funding period of the grant.

K25:

- Are the proposed research question, design, and methodology of significant scientific and technical merit?
- Is the research plan relevant to the candidate's research career objectives?
- Is the research plan appropriate to the stage of research development and as a vehicle for developing the research skills described in the career development plan?

K99:

- Is the proposed K99 phase research significant?
- Are the scientific and technical merits of the K99 research question, experimental design and methodology appropriate for the candidate's level of training, an appropriate vehicle for developing the research skills described in the career development plan, and appropriate for developing a highly successful R00 research program?
- Is the proposed R00 phase research scientifically sound and a logical extension of the K99 phase research?
- Is there evidence of long-term viability of the proposed R00 phase research plan?
- Evaluate the innovation and creativity of the proposed R00 phase research, i.e., does the project address an innovative hypothesis or challenge existing paradigms?
- Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies?
- To what extent is the proposed R00 phase research likely to contribute significantly to our understanding of biomedical problems?
- To what extent is proposed R00 phase research likely to foster the career of the candidate as an independent investigator in biomedical research?

4. Mentor(s), Consultant(s), Collaborator(s)

K01 and K08:

- Are the mentor's research qualifications in the area of the proposed research appropriate?

- Do the mentor(s) adequately address the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of previous research productivity and peer-reviewed support?
- Is there active/pending support for the proposed research project appropriate and adequate?
- Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K23:

- Are the mentor's research qualifications in the area of the proposed patient-oriented research appropriate?
- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate?
- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of previous research productivity and peer-reviewed support focusing on patient-oriented research?
- Is there active/pending support for the proposed research project appropriate and adequate?
Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K24:

- Is there adequate information provided that clearly documents expertise in the proposed area(s) of consulting/collaboration?

K25:

- Are the mentor's research qualifications in the area of the proposed research appropriate?
- Do the mentor(s) adequately address the above review criteria including the candidate's potential and his/her strengths and areas needing improvement?
- Is there adequate description of the quality and extent of the mentor's proposed role in providing guidance and advice to the candidate?
- Is there evidence of the mentor's, consultant's, collaborator's previous experience in fostering the development of independent investigators?
- Is there evidence of previous productivity and peer-reviewed support in area of basic or clinical biomedical, bioengineering, bioimaging or behavioral research?
- Is there active/pending support for the proposed research project appropriate and adequate?
- Is the mentor's description of the elements of the research career development activities, including formal course work adequate? Are there adequate plans for monitoring and evaluating the career development awardee's progress toward independence?

K99:

- To what extent does the mentor have a strong track record in training future independent researchers?

- To what extent are the mentor's research qualifications and experience, scientific stature, and mentoring track record appropriate for the applicant's career development needs?
- Does the mentor(s) adequately address the above review criteria including the candidate's potential as well as his/her strengths and areas needing improvement?
- Evaluate the nature and extent of the proposed supervision that will occur during the mentored phase of support, i.e. is it adequate, and is the commitment of the mentor(s) to the applicant's continued career development appropriate?
- Does the mentor have a comprehensive plan to support the proposed K99 phase career development and research plans as well as the candidate's efforts to transition to independence?
- Is this plan adequate and appropriate?
- Are the consultants'/collaborators' research and/or mentoring qualifications appropriate for their roles in the proposed K99 phase of the award?

5. Environment and Institutional Commitment to the Candidate

K01, K08, K23, and K25:

- Is there clear commitment of the sponsoring institution to ensure that a minimum of 75% of the candidate's effort will be devoted directly to the research described in the application, with the remaining percent effort being devoted to an appropriate balance of research, teaching, administrative, and clinical responsibilities?
- Is the institutional commitment to the career development of the candidate appropriately strong?
- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?
- Is there assurance that the institution intends the candidate to be an integral part of its research program?

K24:

- Is the level of the applicant institution's commitment to the scientific development of the candidate appropriate?
- Is the level of assurance from the institution that they intend the candidate to be an integral part of its patient-oriented research program adequate?
- Are the research facilities, resources and appropriate educational opportunities available to the candidate appropriate and adequate?
- Are the size and quality of the pool of clinician investigators to be mentored by the PI/PD adequate? Are the quality and relevance of the environment for continuing the scientific and professional development of the candidate and for others pursuing patient-oriented research appropriate and adequate?
- Is the commitment from the sponsoring institution to provide adequate protected time for the candidate to conduct the research and mentoring program adequate?
- Is the level of commitment of the candidate's institution to the career development in patient-oriented research of new clinical investigators mentored by the candidate adequate?

K99:

- To what extent does the institution provide a high quality environment for the candidate's development?
- To what extent are the research facilities and educational opportunities, including collaborating faculty, adequate and appropriate for the candidate's research and career development goals during the K99 phase of the award?
- What evidence is provided that the K99 sponsoring institution is strongly committed to fostering the candidate's development and transition to the independent (R00) phase?

- Is there adequate assurance that the required (minimum of 75%) effort of the candidate will be devoted directly to the research training, career development, and research activities described in the proposed career development and research plans?

ADDITIONAL REVIEW CRITERIA

As applicable for the project proposed, reviewers will consider the following additional items in the determination of scientific and technical merit, but will not give separate scores for these items.

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46 (as described in Human Subjects Protection and Inclusion), reviewers are asked to evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria:

- 1) risk to subjects,
- 2) adequacy of protection against risks,
- 3) potential benefits to the subjects and others,
- 4) importance of the knowledge to be gained, and
- 5) data and safety monitoring for clinical trials.

If all of the criteria are adequately addressed, and there are no concerns, write "Acceptable Risks and/or Adequate Protections." A brief explanation is advisable.

If one or more criteria are inadequately addressed, write, "Unacceptable Risks and/or Inadequate Protections" and document the actual or potential issues that create the human subjects concern. Also, if a clinical trial is proposed, evaluate the Data and Safety Monitoring Plan. (If the plan is absent, notify the SRO immediately to determine if the application should be withdrawn.) Indicate if the plan is "Acceptable" or "Unacceptable", and, if unacceptable, explain why it is unacceptable.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt, evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. If the claimed exemption is not justified, indicate "Unacceptable", and, if unacceptable, explain why it is unacceptable.

NOTE: To the degree that acceptability or unacceptability affects the investigator's approach to the proposed research, such comments should appear under "Approach" in the five major review criteria above, and should be factored into the score as appropriate. For additional information to assist you in making these determinations, please refer to Human Subjects Protection and Inclusion.

Inclusion of Women, Minorities, and Children:

When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. Public Law 103-43 requires that women and minorities must be included in all NIH-supported clinical research projects involving human subjects unless a clear and compelling rationale establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. NIH requires that children (individuals under the age of 21) of all ages be involved in all human subjects research supported by the NIH unless there are scientific or ethical reasons for excluding them.

Each project involving human subjects must be assigned a code using the categories "1" to "5" below. Category 5 for minority representation in the project means that only foreign subjects are in the study population (no U.S. subjects). If the study uses both then use codes 1 thru 4.

Examine whether the minority and gender characteristics of the sample are scientifically acceptable, consistent with the aims of the project, and comply with NIH policy. For each category, determine if the proposed subject recruitment targets are "A" (acceptable) or "U" (unacceptable). If you rate the sample as "U", consider this feature a weakness in the research design and reflect it in the overall score. Explain the reasons for the recommended codes; this is particularly critical for any item coded "U".

Gender Inclusion Code	Minority Inclusion Code	Children Inclusion Code
G1 = Both genders	M1 = Minority and nonminority	C1 = Children and adults
G2 = Only women	M2 = Only minority	C2 = Only children
G3 = Only men	M3 = Only nonminority	C3 = No children included
G4 = Gender composition unknown	M4 = Minority composition unknown	C4 = Representation of children unknown
	M5 = Only foreign subjects	

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points:

- 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used;
- 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed;
- 3) adequacy of veterinary care;
- 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and
- 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.

For additional information to assist you in determining if the Vertebrate Animals section is "Acceptable" or "Unacceptable", please refer to Vertebrate Animals checklist.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmission

When reviewing a Resubmission application (formerly called an amended application), please evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewal

K01, K08, K23, K99.

This award may not be renewed.

K24

When reviewing a Renewal application (formerly called a competing continuation application), the committee the committee will consider the following questions.

- Has there been adequate progress in achieving the career, research, and/or mentoring objectives of the previous award period? Is the justification provided for an additional 3 to 5

years of support adequate? (This requires that the recipient continue to have independent peer-reviewed research support at the time of submission of the renewal application; and documentation of a continuing need for protected time to expand the program and the mentoring activities supported during the prior funding period of the award).

- Does the PD/PI adequately demonstrate the continuing need for protected time to expand his/her research and mentoring program?
- Is there evidence of the PD/PI's continuing leadership in patient-oriented research through, for example, being principal investigator on new independent peer-reviewed research grants and providing high quality mentorship?

ADDITIONAL REVIEW CONSIDERATIONS

As applicable for the project proposed, reviewers will address each of the following items, but will not give scores for these items and should not consider them in providing an overall impact score

Training in the Responsible Conduct of Research

Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration, and Frequency of instruction), as detailed in NOT-OD-10-019. Plans and past record will be rated as ACCEPTABLE or UNACCEPTABLE.

Select Agents.

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s). Select agent information is available via

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable.

Sharing Model Organisms: All NIH grant applications are expected to include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding or state why such sharing is restricted or not possible.

Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is NOT subject to a cost threshold of \$500,000 or more in direct costs in any one year, and is expected to be included in all applications where the development of model organisms is anticipated.

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>)

Genome Wide Association Studies: Applications and proposals that include GWAS, regardless of the requested costs, are expected to include as part of the Research Plan either a plan for submission of GWAS data to the NIH designated data repository or an appropriate explanation for why submission to the repository will not be possible. (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html>)

Budget and Period of Support

Is the proposed budget and period of support appropriate in relation to the proposed research and the career development needs of the candidate?

ADDITIONAL COMMENTS TO APPLICANT

Reviewers may provide guidance to the applicant or recommend against resubmission without fundamental revision.